

## PROCEDURES FOR USDA APHIS PERMITS FOR TRANSGENIC ARTHROPODS AND OTHER INVERTEBRATES THAT ARE PLANT PESTS

1. Applicants are encouraged to telephone or arrange a meeting to discuss the requirement for an APHIS permit for a transgenic arthropod or invertebrate plant pests.
2. If it is determined that a permit is not required or the organism is not regulated under the provisions of 7 CFR Part 340, the applicant may request a Regulatory Opinion letter from the Agency.
3. If it is determined that the organism is regulated under 7 CFR Part 340 and a permit is required, Form 2000 (USDA, APHIS, Biotechnology, Biologics, and Environmental Protection Application for Permit or Courtesy Permit) must be used and is available at URL: <http://www.aphis.usda.gov/forms/>
4. Complete Form 2000 and submit it with supporting documents to:

USDA, APHIS, PPQ  
Permits and Risk Assessment  
Biotechnology Unit  
4700 River Road, Unit 147  
Riverdale, MD 20737  
Fax: (301) 734-8669

The applicant is also requested to submit an electronic version or file of their application for a permit. Prepare the notification as you would normally on your computer and save it as ASCII text.

5. The permit application is first reviewed for presence of all the required information. Missing information or completion of deficiencies may be requested, or the application may be returned as incomplete.
6. The 120-day interval for completion of the review process is initiated upon determination that the application is complete.
7. The application will be made available to the public, without confidential business information (CBI), on the APHIS web site.
8. APHIS records are reviewed to determine if a related or similar organism have previously been permitted. If one has, and a review indicates that there are no significant differences between the organisms in respect to plant pest or environmental risks, then the review is expedited.
9. The preliminary review process is completed and the respective State(s) is/are notified that an application to release a transgenic organism in their State has been received, that APHIS has determined that the proposed release involves a regulated article under 7 CFR Part 340, and that APHIS will complete an assessment of the proposed release and submit the assessment to the State(s) for concurrence or comment.

**10.** If the assessment concludes that the proposed release of the transgenic organism poses a significant threat to plants or the environment, a permit may be declined. The applicant and State(s) are informed of the basis of the decision and availability of an appeal process.

**11.** The assessment may also conclude that the proposed release of the transgenic arthropod poses some risk to crops or the environment, however, mitigating measures may be available to reduce risk. The applicant is advised accordingly, the 120-day review interval is stopped, and discussions between the applicant, APHIS, and possibly the affected State(s) continue until agreement on mitigations is reached or the application is withdrawn.

**12.** The assessment may also conclude that there is no significant risk to plants or the environment.

**13.** The draft assessment is submitted to the respective State(s) for their review and concurrence within 30 days.

**14.** The State(s) may concur, without adding any conditions or they may require conditions. Subsequent consultations between APHIS, the State(s), and applicant may occur to obtain agreement on conditions for release. The State(s) may also not concur. Consultations may then occur between APHIS, the State(s), and applicant to resolve issues.

**15.** Upon State(s) concurrence, APHIS determines if the action or decision may be categorically excluded from the requirement of an environmental assessment (EA) under the National Environmental Policy Act (NEPA) as described in 7 CFR § 372.5(c). If an EA is not required, an APHIS permit may then be issued.

**16.** If a § 372.5(c) APHIS NEPA categorical exclusion does not apply, an EA is prepared. The EA process may often include Endangered Species Act requirements and consultation with the Fish and Wildlife Service. The EA is made available to the public for a 30-day comment period by an announcement of availability in the Federal Register (FR). A docket location to submit comments is provided in the FR notice.

**17.** Public comments on the EA are evaluated for significance. When they are objective and supported by rationale, data, references, or other information, they are given due consideration in the decision to produce either a finding of no significant impact (FONSI) or environmental impact statement (EIS). Also, the EA may be rewritten taking the public comments into due consideration. When a FONSI is produced, a permit may then be issued. If it is decided to prepare an EIS, the permit process will be delayed or the application may be withdrawn, obviating the need for an EIS.

**18.** Once a permit is issued and the activity has begun, inspections are made to assure compliance with the conditions of the permit and for any irregularities.

**19.** A report must be submitted within six months after the termination of the field test. Adverse effects or incidents involving the activity must be reported immediately after they occur or when they are first observed.